



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **45 CFR Part 1330**

### **RIN 0985-AA12**

### **National Institute on Disability, Independent Living, and Rehabilitation Research**

**AGENCY:** National Institute on Disability, Independent Living, and Rehabilitation Research; Administration for Community Living; HHS.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would implement the Workforce Innovation and Opportunity Act of 2014 and reflect the transfer of the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) from the Department of Education to the Department of Health and Human Services. The previous regulations were issued by the Department of Education. The rulemaking will consolidate the NIDILRR regulations into a single part, align the regulations with the current statute and HHS policies, and will provide guidance to NIDILRR grantees.

**DATES:** Comments are due on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** You may submit comments in one of following ways (no duplicates, please):

Written comments may be submitted through any of the methods specified below. Please do not submit duplicate comments.

- **Federal eRulemaking Portal:** You may (and we encourage you to) submit electronic comments on this regulation at <http://www.regulations.gov>. Follow the instructions under the “submit a comment” tab. Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.

- Regular, Express, or Overnight Mail: You may mail written comments to the following address ONLY: Administration for Community Living, Attention: NIDILRR NPRM, U.S. Department of Health and Human Services, Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.
- Individuals with a Disability: We will provide an appropriate accommodation, including alternative formats, upon request. To make such a request, please contact Marlina Moses-Gaither, (202) 795-7409 (Voice) or at [marlina.moses-gaither@acl.hhs.gov](mailto:marlina.moses-gaither@acl.hhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Greg Pugh, Administration for Community Living, telephone (202) 795-7422 (Voice). This is not a toll-free number. This document will be made available in alternative formats upon request.

## **SUPPLEMENTARY INFORMATION:**

### **I. Workforce Innovation and Opportunity Act of 2014**

The Workforce Innovation and Opportunity Act of 2014 (“WIOA,” Public Law 113-128), signed into law on July 22, 2014, included significant changes to Title II of the Rehabilitation Act of 1973. The first of these is the insertion of a new name, the National Institute on Disability, Independent Living, and Rehabilitation Research (“NIDILRR,” which was previously the National Institute on Disability and Rehabilitation Research). WIOA also relocates NIDILRR from the Department of Education (“ED”) to the Administration for Community Living (“ACL”) of the Department of Health and Human Services.

### **II. Programs Authorized by Title II of the Rehabilitation Act of 1973, as amended by WIOA**

#### **A. Disability, Independent Living, and Rehabilitation Research Projects and Centers**

The purpose of the Disability and Rehabilitation Research Projects and Centers program is to plan and conduct research, development, demonstrations, training, dissemination, and related activities, including international activities, to maximize the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities, and improve the effectiveness of services authorized under the Rehabilitation Act of 1973, 29 U.S.C. 701 et seq.

To this end, NIDILRR provides grants to establish and support:

- Disability, Independent Living, and Rehabilitation Research Projects;
- Field Initiated Projects;
- Advanced Rehabilitation Research Training Projects;
- Rehabilitation Research and Training Centers; and
- Rehabilitation Engineering Research Centers.

Eligible entities for awards under this program include States, public or private agencies and organizations, institutions of higher education, and Indian tribes and tribal organizations.

## **B. Research Fellowships**

The purpose of the Research Fellowships program is to build research capacity by providing support to highly qualified individuals, including those who are individuals with disabilities, to perform research on rehabilitation and independent living of individuals with disabilities. Any individual is eligible for assistance under this program who has training and experience that indicate a potential for engaging in scientific research related to the solution of rehabilitation problems of individuals with disabilities. The program provides grants to support two categories of Fellowships: Distinguished Fellowships (for those with seven or more years of relevant

research experience) and Merit Fellowships (for individuals in earlier stages of their careers in research).

### **C. Special Projects and Demonstrations for Spinal Cord Injuries**

The Special Projects and Demonstrations for Spinal Cord Injuries program provides assistance to establish innovative projects for the delivery, demonstration, and evaluation of comprehensive medical, vocational, and other rehabilitation services to meet the wide range of needs, including independent living, of individuals with spinal cord injuries. The entities eligible for an award under these Projects and Demonstrations are the same as for Disability and Rehabilitation Research Projects and Centers.

### **III. Discussion of Proposed Rule**

Department of Education regulations governing the National Institute on Disability and Rehabilitation Research are found at 34 CFR parts 350, 356, and 359. Part 350 sets forth regulations addressing the Disability and Rehabilitation Research Projects and Centers Program; part 356 sets forth regulations addressing Disability and Rehabilitation Research Fellowships; and part 359 sets forth regulations addressing Special Projects and Demonstrations for Spinal Cord Injuries. ACL proposes to streamline the NIDILRR regulations and to consolidate them into one part, 45 CFR part 1330. In our regulations, we propose to eliminate regulatory language included in the corresponding ED regulations that does not add further interpretation to the statutory language. We also propose to eliminate unnecessary regulatory language that already exists in other documents and that need not be included in regulatory language, such as the application materials or terms and conditions of grant awards. The remainder of the proposed rule is derived largely from the previous ED language, with significant deviations noted below.

#### **45 CFR Part 1330**

We propose creating a new part to 45 CFR, part 1330, entitled National Institute for Disability, Independent Living, and Rehabilitation Research. We expect the Department of Education will be issuing regulations at a later date rescinding 34 CFR parts 350, 356, and 359.

**Subpart A – Disability, Independent Living, and Rehabilitation Research Projects and Centers Program**

Subpart A will contain general requirements for the main NIDILRR grant program.

Proposed § 1330.1 explains what projects are funded under the program, and the purpose of the program. This section will provide a valuable framework to potential applicants for NIDILRR funding, as the statute does not specify specific funding opportunities. The provisions largely incorporate language from the corresponding regulations at 34 CFR 350.1 and 350.2.

Proposed § 1330.2 contains information on what entities are eligible to receive assistance under the program, and is derived substantially from the authorizing statute. It also cites other regulations that apply to the awards under part 1330, including the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, codified at part 75 of 45 CFR, rather than the EDGAR regulations which govern Department of Education financial assistance. In addition, all entities receiving assistance are subject to the HHS Grants Policy Statement, available at <http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>. Other than citing to the HHS Grant and other applicable regulations, the proposed rule is generally the same as 34 CFR 350.3 and 350.4.

Proposed § 1330.3 contains definitions of terms used throughout the proposed rules.

Proposed § 1330.4 defines the stages of research funded by NIDILRR, and requires applicants to identify which stage(s) of research they propose to undertake. This is a significant addition as compared to existing ED regulations and represents a major safeguard to NIDILRR's scientific

integrity. We believe that asking applicants to identify the stage of research they are proposing would help applicants clarify the expected outcomes of their proposed research and would help us better categorize our research investments and tailor our review process. The proposed change would also help us select reviewers who are knowledgeable about the topic and able to assess the relationship between the identified stage of research and the proposed research design. This would increase the likelihood that we fund research that contributes to the evolution of knowledge on a topic. The stages of research reflect a progression in the development of knowledge from describing the status, needs, and challenges of individuals with disabilities to developing and testing interventions to widespread adoption of effective practices, programs, and policies that improve their status, respond to their needs, and reduce their challenges with the aim of supporting independence, integration, productivity, and self-determination.

Proposed § 1330.5 defines the stages of development funded by NIDILRR, and applicants are expected to identify which stage(s) of development they propose to undertake. We believe that asking applicants to identify the stage(s) of development will help them to better document and communicate proposed development projects and expected outcomes and help us better categorize development projects, select reviewers, and tailor our review process. This will increase the likelihood of funding development projects that contribute to products meeting significant needs of individuals with disabilities. ACL especially solicits comments on these stages of development, and the addition of a requirement to identify the stage(s) of development proposed for funding.

#### **Subpart B – Requirements for Awardees**

Subpart B contains general requirements for awardees under the NIDILRR research program.

Proposed § 1330.10 identifies the activities which are eligible to receive funding.

Proposed § 1330.11, in accordance with 29 U.S.C. 718(c), when so indicated in application materials or elsewhere, requires applicants to demonstrate in their applications how they will address the needs of people with disabilities from minority backgrounds.

### **Subpart C – Selection of Awardees**

Subpart C describes what processes NIDILRR will use in the selection of awardees.

Proposed § 1330.20 explains the purpose and importance of peer review

Proposed § 1330.21 states that peer review will be used in the selection of awardees. Peer review is viewed as integral to the continuing independence and scientific integrity of NIDILRR’s work. In addition, 29 U.S.C. 762(f)(1) provides that the NIDILRR Director “shall provide for scientific peer review of all applications for financial assistance for research, training, and demonstration projects over which the Director has authority.”

Proposed § 1330.22 establishes the composition of peer review panels, and the factors used by the Director to select members for these panels. In accordance with 29 U.S.C. 762(f)(1), employees of the U.S. Department of Health and Human Services are excluded from peer review panels.

Proposed § 1330.23 contains the evaluation process used in determining which applications to fund, including the selection of evaluation criteria, scoring, and notification requirements. This process is largely statutory, stating that the selection criteria are based on statutory provisions that apply to the Program.

Proposed § 1330.24 is an extensive list of criteria from which the Director may select in evaluating applications, and for the most part is verbatim of § 350.54 of 34 CFR. An important proposed addition to § 1330.24 is language which allows for the assessment of either hypotheses or research questions, as appropriate to the proposed research. In addition, language is proposed

which adds clarity as to the evaluation of the “appropriateness” of research samples, specifically two elements: the extent to which the sampling process yields research participants who are appropriate to the purpose of the study (i.e., representative and inclusive of social, ethnic, socioeconomic, disability-related, and other differences that are important to the outcomes and implications of the research); and whether the sample size is sufficient to reasonably expect that differences resulting from the proposed intervention can be detected in the population being studied.

We also propose a factor for assessing the feasibility of implementing a proposed research design. This factor will assist peer reviewers to evaluate the quality of the research design, and whether it can be successfully completed, especially in light of the time and resources available. We propose to add this assessment factor to ensure that we sponsor high-quality research that can be carried out by the applicant. Without a factor related to feasibility, we could fund technically well-designed research proposals that cannot realistically be completed, given limitations in time, resources, and current knowledge.

Additional proposed factors in this rule not included in ED regulations include the extent to which applicants obtain and use input from individuals with disabilities and other stakeholders to shape the proposed research activities. Another proposed factor requires that applicants identify and justify the stage of research to establish that the proposed research has a foundation in the current state of knowledge on the topic.

An important proposed addition to this section is a factor which allows for the assessment of development projects. Proposed factors and sub-factors are intended to improve the rigor and clarity of documentation and communication for proposed development projects; facilitate high quality peer-review; and subsequent management and oversight of funded projects.



Conceptually, these factors span the research basis supporting a significant need and target population for a product; methodological elements common and appropriate to most development projects; and demonstration that the product is or is likely to be adopted by the target population and used for its intended purpose. ACL particularly solicits comments on this factor.

Proposed § 1330.25 contains selection criteria specifically for field-initiated priorities New to proposed § 1330.25 is authority for NIDILRR to fund out of rank order for all competitions conducted under § 1330.25 provided that the application receives a peer review score of at least 80 percent or more of available points and represents a unique opportunity to advance the rehabilitation knowledge to improve the lives of individuals with disabilities, complements research investment already planned or funded, or addresses research in a new and promising way. This will allow NIDILRR to take advantage of a unique opportunity to advance the field, complement our investment in a particular research area, or build capacity in one of our research domains or broad priority areas, while maintaining quality standards.

#### **Subpart D – Disability, Independent Living, and Rehabilitation Research Fellowships**

Subpart D contains information on programs awarding funding to research fellows, along with the eligibility requirements and selection criteria for these programs. This is significantly streamlined as compared to part 356 in the ED rules, but is included to signify that the program discussed in that part continue under HHS’ administration. In keeping with established ED practice, these fellowships will be funded by grants to eligible fellows, as HHS believes that this supports the development of new and existing researchers in the fields of disability, independent living, and rehabilitation research.

#### **Subpart E – Special Projects and Demonstrations for Spinal Cord Injuries**

Subpart E contains information on projects focusing on spinal cord injuries and eligibility requirements for these awards. This is significantly streamlined as compared to part 359 in the ED rules, but is included for the reasons stated in subpart D.

**Existing ED regulations not carried over to this proposed rule are as follows:**

ED Citation	Title	Reason for Deletion
§ 350.10	What are the general requirements for Disability and Rehabilitation Research Projects?	Summarizes Rehabilitation Act, does not add new information.
§ 350.11	What are the general requirements for a Field-Initiated Project?	Summarizes Rehabilitation Act, does not add new information.
§ 350.12	What are the general requirements for an Advanced Rehabilitation Research Training Project?	Summarizes Rehabilitation Act, does not add new information.
Part 350, Subpart C	What Rehabilitation Research and Training Centers Does the Secretary Assist?	Summarizes Rehabilitation Act, does not add new information.
Part 350, Subpart D	What Rehabilitation Engineering Research Centers Does the Secretary Assist?	Summarizes Rehabilitation Act, does not add new information. Requirements for advisory committees from § 350.34 and § 350.35 will be included in application materials and grant terms & conditions, where appropriate.
§ 350.41	What State agency review must an applicant under the Disability and Rehabilitation Research Projects and Centers Program obtain?	No longer used by NIDILRR.
Part 350, Subpart G	What Conditions Must Be Met After an Award?	Requirements are either already stated in the statute or are subject to the HHS-specific award requirements. In addition, other post-award conditions may be included in application materials and grant terms & conditions, where appropriate.
§ 356.3	What regulations apply to this program?	Same regulations apply as in § 1330.4.
§ 356.4	What definitions apply to this program?	Not used by NIDILRR.
Part 356, Subpart B	What Kinds of Activities Does the Department Support Under This Program?	Not used by NIDILRR.
Part 356,	How Does One Apply For Assistance	Subject to same requirements as

Subpart C	Under This Program?	established in § 1330.10.
Part 356, Subpart D	How Does the Secretary Select a Fellow	Subject to same criteria as established in § 1330.23.
Part 356, Subpart E	What Conditions Have To Be Met By A Fellow?	When not already stated in statute, requirements will be included in application materials, terms & conditions, or contract requirements where appropriate.
Part 356, Subpart F	What Are the Administrative Responsibilities of a Fellow?	When not already stated in statute, requirements will be included in application materials, terms & conditions, or contract requirements where appropriate.
§ 359.3	What regulations apply to this program?	Same regulations apply as in § 1330.4.
§ 359.4	What definitions apply to this program?	Not used by NIDILRR.
Part 359, Subpart B	What Kinds of Activities Does the Secretary Assist Under This Program?	Summarizes Rehabilitation Act, does not add new information.
§ 359.30	How is peer review conducted under this program?	Same as in part 1330, subpart C.
§ 359.31	What selection criteria does the Secretary use in reviewing applications under this program?	Same as in part 1330, subpart C.
§ 359.32	What additional factors does the Secretary consider in making a grant under this program?	Summarizes Rehabilitation Act, does not add new information.

#### **IV. Impact Analysis**

##### **A. Executive Orders 12866 and 13563**

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives, and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Department has determined that this proposed rule is consistent with the priorities and principles set forth in Executive Order 12866. Executive Order 12866 encourages agencies, as appropriate, to provide the public with meaningful participation in the regulatory process. The rulemaking implements the Workforce

Innovation and Opportunity Act of 2014. In developing the final rule, we will consider input we received from the public including stakeholders. This proposed rule is not being treated as a “significant regulatory action” under section 3(f)(1) of Executive Order 12866. Accordingly, the proposed rule has not been reviewed by the Office of Management and Budget.

### **B. Regulatory Flexibility Analysis**

The Secretary certifies under 5 U.S.C. 605(b), the Regulatory Flexibility Act (Public Law 96-354), that this regulation will not have a significant economic impact on a substantial number of small entities. The primary impact of this proposed regulation is on entities applying for NIDILRR funding opportunities, specifically researchers, States, public or private agencies and organizations, institutions of higher education, and Indian tribes and tribal organizations. The proposed regulation does not have a significant economic impact on these entities. This proposed rule is in fact significantly shorter than, but with identical compliance requirements to, the regulations it replaces.

### **C. Paperwork Reduction Act of 1995**

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the Federal Register and solicit public comment before an information collection request is submitted to the Office of Management and Budget (OMB) for review and approval. We are not introducing any new information collections in this proposed rule however, nor revising reporting requirements.

### **D. Unfunded Mandates Reform Act**

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) requires that a covered agency prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in expenditures by State, local, or Tribal

governments, in the aggregate, or by the private sector, of \$100 million, adjusted for inflation, or more in any one year.

If a covered agency must prepare a budgetary impact statement, section 205 further requires that it select the most cost-effective and least burdensome alternatives that achieves the objectives of the rule and is consistent with the statutory requirements. In addition, section 203 requires a plan for informing and advising any small government that may be significantly or uniquely impacted by a rule.

ACL has determined that this proposed rule does not result in the expenditure by State, local, and Tribal governments in the aggregate, or by the private sector of more than \$100 million in any one year.

#### **E. Congressional Review**

This proposed rule is not a major rule as defined in 5 U.S.C. Section 804(2).

#### **F. Assessment of Federal Regulations and Policies on Families**

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires Federal agencies to determine whether a policy or regulation may affect family well-being. If the agency's conclusion is affirmative, then the agency must prepare an impact assessment addressing seven criteria specified in the law. These proposed regulations do not have an impact on family well-being as defined in the legislation.

#### **G. Executive Order 13132**

Executive Order 13132 on "federalism" was signed August 4, 1999. The purposes of the Order are: "...to guarantee the division of governmental responsibilities between the national government and the States that was intended by the Framers of the Constitution, to ensure that

the principles of federalism established by the Framers guide the executive departments and agencies in the formulation and implementation of policies, and to further the policies of the Unfunded Mandates Reform Act...”

The Department certifies that this proposed rule does not have a substantial direct effect on States, on the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government.

ACL is not aware of any specific State laws that would be preempted by the adoption of the regulation.

Dated: December 15, 2015.

**Kathy Greenlee,**

Administrator

Administration for Community Living

Approved: December 15, 2015.

**Sylvia M. Burwell**

Secretary

U.S. Department of Health and Human Services

## **List of Subjects in 45 CFR Part 1330**

Grant programs, Research, Scholarships and fellowships.

For reasons set forth in the preamble, under the authority at 29 U.S.C. 709 and 3343, the Department of Health and Human Services proposes to add part 1330 of subchapter C title 45 to read as set forth below:

### **PART 1330 – NATIONAL INSTITUTE FOR DISABILITY, INDEPENDENT LIVING, AND REHABILITATION RESEARCH**

Subpart A – Disability, Independent Living, and Rehabilitation Research Projects and Centers Program

Sec.

1330.1 General.

1330.2 Eligibility for assistance and other regulations and guidance.

1330.3 Definitions.

1330.4 Stages of research.

1330.5 Stages of development.

Subpart B – Requirements for Awardees

1330.10 General requirements for awardees.

1330.11 Individuals with disabilities from minority backgrounds.

Subpart C – Selection of Awardees

1330.20 Peer review purpose.

1330.21 Peer review process.

1330.22 Composition of peer review panel.

1330.23 Evaluation process.

1330.24 Selection criteria.

1330.25 Additional considerations for field-initiated priorities.

Subpart D – Disability, Independent Living, and Rehabilitation Research Fellowships

1330.30 Fellows program.

Subpart E – Special Projects and Demonstrations for Spinal Cord Injuries



1330.40 Spinal cord injuries program.

Authority: 29 U.S.C. 709, 3343

**Subpart A - Disability, Independent Living, and Rehabilitation Research Projects and Centers Program**

**§ 1330.1 General.**

(a) The Disability, Independent Living, and Rehabilitation Research Projects and Centers

Program provides grants to establish and support—

(1) The following Disability, Independent Living, and Rehabilitation Research and

Related Projects:

(i) Disability, Independent Living, and Rehabilitation Research Projects;

(ii) Field-Initiated Projects;

(iii) Advanced Rehabilitation Research Training Projects; and

(2) The following Disability, Independent Living, and Rehabilitation Research Centers:

(i) Rehabilitation Research and Training Centers;

(ii) Rehabilitation Engineering Research Centers.

(b) The purpose of the Disability, Independent Living, and Rehabilitation Research Projects and

Centers Program is to plan and conduct research, development, demonstration projects, training,

dissemination, and related activities, including international activities, to—

(1) Develop methods, procedures, and rehabilitation technology, that maximize the full

inclusion and integration into society, employment, education, independent living, family

support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities; and

(2) Improve the effectiveness of services authorized under the Rehabilitation Act of 1973, 29 U.S.C. 701 et seq.

**§ 1330.2 Eligibility for assistance and other regulations and guidance.**

(a) Unless otherwise stated in this Part or in a determination by the NIDILRR Director, the following entities are eligible for an award under this program:

- (1) States.
- (2) Public or private agencies, including for-profit agencies.
- (3) Public or private organizations, including for-profit organizations.
- (4) Institutions of higher education.
- (5) Indian tribes and tribal organizations.

(b) Other sources of regulation which may apply to awards under this part include but are not limited to:

- (1) 45 CFR part 16 – Procedures of the Departmental Grant Appeals Board.
- (2) 45 CFR part 46 – Protection of Human Subjects.
- (3) 45 CFR part 75 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Award.
- (4) 2 CFR parts 376 and 382 – Nonprocurement Debarment and Suspension and Requirements for Drug-Free Workplace (Financial Assistance).
- (5) 45 CFR part 80 – Nondiscrimination under Programs Receiving Federal Assistance through the Department of Health and Human Services – Effectuation of title VI of the Civil Rights Act of 1964.

(6) 45 CFR part 81 – Practice and Procedures – Practice and Procedure for Hearings Act under part 80 of this title.

(7) 45 CFR part 84 – Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting from Federal Financial Assistance.

(8) 45 CFR part 86 – Nondiscrimination on the Basis of Sex in Education Programs and Activities Receiving or Benefiting from Federal Financial Assistance.

(9) 45 CFR part 87 – Equal Treatment of Faith-Based Organizations.

(10) 45 CFR part 91 – Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance from HHS.

(11) 45 CFR part 93 – New Restrictions on Lobbying.

### **§ 1330.3 Definitions.**

As used in this part:

(a) *Secretary* means the Secretary of the Department of Health and Human Services

(b) *Administrator* means the Administrator of the Administration for Community Living

(c) *Director* means the Director of the National Institute on Disability, Independent Living, and Rehabilitation Research.

(d) *Research* is classified on a continuum from basic to applied:

(1) *Basic research* is research in which the investigator is concerned primarily with gaining new knowledge or understanding of a subject without reference to any immediate application or utility.

(2) *Applied research* is research in which the investigator is primarily interested in developing new knowledge, information, or understanding which can be applied to a predetermined rehabilitation problem or need.

(e) *Development activities* use knowledge and understanding gained from research to create materials, devices, systems, or methods beneficial to the target population, including design and development of prototypes and processes.

#### **§ 1330.4 Stages of research.**

For any Disability, Independent Living, and Rehabilitation Research Projects and Centers Program competition, the Department may require in the application materials for the competition that the applicant identify the stage(s) of research in which it will focus the work of its proposed project or center. The four stages of research are—

(a) Exploration and discovery mean the stage of research that generates hypotheses or theories through new and refined analyses of data, producing observational findings and creating other sources of research-based information. This research stage may include identifying or describing the barriers to and facilitators of improved outcomes of individuals with disabilities, as well as identifying or describing existing practices, programs, or policies that are associated with important aspects of the lives of individuals with disabilities. Results achieved under this stage of research may inform the development of interventions or lead to evaluations of interventions or policies. The results of the exploration and discovery stage of research may also be used to inform decisions or priorities;

(b) Intervention development means the stage of research that focuses on generating and testing interventions that have the potential to improve outcomes for individuals with disabilities. Intervention development involves determining the active components of possible interventions, developing measures that would be required to illustrate outcomes, specifying target populations, conducting field tests, and assessing the

feasibility of conducting a well-designed intervention study. Results from this stage of research may be used to inform the design of a study to test the efficacy of an intervention;

(c) Intervention efficacy means the stage of research during which a project evaluates and tests whether an intervention is feasible, practical, and has the potential to yield positive outcomes for individuals with disabilities. Efficacy research may assess the strength of the relationships between an intervention and outcomes, and may identify factors or individual characteristics that affect the relationship between the intervention and outcomes. Efficacy research can inform decisions about whether there is sufficient evidence to support “scaling-up” an intervention to other sites and contexts. This stage of research may include assessing the training needed for wide-scale implementation of the intervention, and approaches to evaluation of the intervention in real-world applications; and

(d) Scale-up evaluation means the stage of research during which a project analyzes whether an intervention is effective in producing improved outcomes for individuals with disabilities when implemented in a real-world setting. During this stage of research, a project tests the outcomes of an evidence-based intervention in different settings. The project examines the challenges to successful replication of the intervention, and the circumstances and activities that contribute to successful adoption of the intervention in real-world settings. This stage of research may also include well-designed studies of an intervention that has been widely adopted in practice, but lacks a sufficient evidence base to demonstrate its effectiveness.

#### **§ 1330.5 Stages of development.**

For any Disability, Independent Living, and Rehabilitation Research Projects and Centers Program competition, the Department may require in the notice inviting applications for the competition that the applicant identify the stage(s) of development in which it will focus the work of its proposed project or center. The three stages of development are--

(a) *Proof of concept* means the stage of development where key technical challenges are resolved. Stage activities may include recruiting study participants, verifying product requirements; implementing and testing (typically in controlled contexts) key concepts, components, or systems, and resolving technical challenges. A technology transfer plan is typically developed and transfer partner(s) identified; and plan implementation may have started. Stage results establish that a product concept is feasible.

(b) *Proof of product* means the stage of development where a fully-integrated and working prototype, meeting critical technical requirements is created. Stage activities may include recruiting study participants, implementing and iteratively refining the prototype, testing the prototype in natural or less-controlled contexts, and verifying that all technical requirements are met. A technology transfer plan is typically ongoing in collaboration with the transfer partner(s). Stage results establish that a product embodiment is realizable.

(c) *Proof of adoption* means the stage of development where a product is substantially adopted by its target population and used for its intended purpose. Stage activities typically include completing product refinements; and continued implementation of the technology transfer plan in collaboration with the transfer partner(s). Other activities include measuring users' awareness of the product, opinion of the product, decisions to

adopt, use, and retain products; and identifying barriers and facilitators impacting product adoption. Stage results establish that a product is beneficial.

## **Subpart B – Requirements for Awardees**

### **§ 1330.10 General requirements for awardees.**

- (a) In carrying out a research activity under this program, an awardee must—
  - (1) Identify one or more hypotheses or research questions;
  - (2) Based on the hypotheses or research question identified, perform an intensive systematic study in accordance with its approved application directed toward—
    - (i) New or full scientific knowledge; or
    - (ii) Understanding of the subject or problem being studied.
- (b) In carrying out a development activity under this program, an awardee must create, using knowledge and understanding gained from research, models, methods, tools, systems, materials, devices, systems, applications, devices, or standards that are adopted by and beneficial to the target population. Development activities span one or more stages of development.
- (c) In carrying out a training activity under this program, an awardee shall conduct a planned and systematic sequence of supervised instruction that is designed to impart predetermined skills and knowledge.
- (d) In carrying out a demonstration activity under this program, an awardee shall apply results derived from previous research, testing, or practice to determine the effectiveness of a new strategy or approach.

(e) In carrying out a utilization activity under this program, a grantee must relate research findings to practical applications in planning, policy making, program administration, and delivery of services to individuals with disabilities.

(f) In carrying out a dissemination activity under this program, a grantee must systematically distribute information or knowledge through a variety of ways to potential users or beneficiaries.

(g) In carrying out a technical assistance activity under this program, a grantee must provide expertise or information for use in problem-solving.

**§ 1330.11 Individuals with disabilities from minority backgrounds.**

(a) If the director so indicates in the application materials or elsewhere, an applicant for assistance under this program must demonstrate in its application how it will address, in whole or in part, the needs of individuals with disabilities from minority backgrounds.

(b) The approaches an applicant may take to meet this requirement may include one or more of the following:

(1) Proposing project objectives addressing the needs of individuals with disabilities from minority backgrounds.

(2) Demonstrating that the project will address a problem that is of particular significance to individuals with disabilities from minority backgrounds.

(3) Demonstrating that individuals from minority backgrounds will be included in study samples in sufficient numbers to generate information pertinent to individuals with disabilities from minority backgrounds.



(4) Drawing study samples and program participant rosters from populations or areas that include individuals from minority backgrounds.

(5) Providing outreach to individuals with disabilities from minority backgrounds to ensure that they are aware of rehabilitation services, clinical care, or training offered by the project.

(6) Disseminating materials to or otherwise increasing the access to disability information among minority populations.

### **Subpart C – Selection of Awardees**

#### **§ 1330.20 Peer review purpose.**

The purpose of peer review is to insure that—

(a) Those activities supported by the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) are of the highest scientific, administrative, and technical quality; and

(b) Activity results may be widely applied to appropriate target populations and rehabilitation problems.

#### **§ 1330.21 Peer review process.**

(a) The Director refers each application for an award governed by those regulations in this part to a peer review panel established by the Director.

(b) Peer review panels review applications on the basis of the applicable selection criteria in § 1330.24.

#### **§ 1330.22 Composition of peer review panel.**

(a) The Director selects as members of a peer review panel scientists and other experts in disability, independent living, rehabilitation or related fields who are qualified, on the

basis of training, knowledge, or experience, to give expert advice on the merit of the applications under review.

(b) The scientific peer review process shall be conducted by individuals who are not Department of Health and Human Services employees.

(c) In selecting members to serve on a peer review panel, the Director may take into account the following factors:

(1) The level of formal scientific or technical education completed by potential panel members.

(2) The extent to which potential panel members have engaged in scientific, technical, or administrative activities appropriate to the category of applications that the panel will consider; the roles of potential panel members in those activities; and the quality of those activities.

(3) The recognition received by potential panel members as reflected by awards and other honors from scientific and professional agencies and organizations outside the Department.

(4) Whether the panel includes knowledgeable individuals with disabilities, or parents, family members, guardians, advocates, or authorized representatives of individuals with disabilities.

(5) Whether the panel includes individuals from diverse populations.

#### **§ 1330.23 Evaluation process.**

(a) The Director selects one or more of the selection criteria in § 1330.24 to evaluate an application;

(1) The Director establishes selection criteria based on statutory provisions that apply to the Program which may include, but are not limited to—

- (A) Specific statutory selection criteria;
- (B) Allowable activities;
- (C) Application content requirements; or
- (D) Other pre-award and post-award conditions; or

(2) The Director may use a combination of selection criteria established under paragraph (a)(1) of this section and selection criteria from § 1330.24 to evaluate a competition.

(3) For Field-Initiated Projects, the Director does not consider § 1330.24(b) (Responsiveness to the Absolute or Competitive Priority) in evaluating an application.

(b) In considering selection criteria in § 1330.24, the Director selects one or more of the factors listed in the criteria, but always considers the factor in § 1330.24(n) regarding members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(c) The maximum possible score for an application is 100 points.

(d) In the application package or a notice published in the FEDERAL REGISTER, the Director informs applicants of—

- (1) The selection criteria chosen and the maximum possible score for each of the selection criteria; and
- (2) The factors selected for considering the selection criteria and if points are assigned to each factor, the maximum possible score for each factor under each

criterion. If no points are assigned to each factor, the Director evaluates each factor equally.

(e) For all instances in which the Director chooses to allow field-initiated research and development, the selection criteria in § 1330.25 will apply, including the requirement that the applicant must achieve a score of 80 percent or more of maximum possible points.

#### **§ 1330.24 Selection criteria.**

In addition to criteria established under § 1330.23(a)(1), the Director may select one or more of the following criteria in evaluating an application:

(a) *Importance of the problem.* In determining the importance of the problem, the Director considers one or more of the following factors:

- (1) The extent to which the applicant clearly describes the need and target population.
- (2) The extent to which the proposed activities further the purposes of the Act.
- (3) The extent to which the proposed activities address a significant need of individuals with disabilities.
- (4) The extent to which the proposed activities address a significant need of rehabilitation service providers.
- (5) The extent to which the proposed activities address a significant need of those who provide services to individuals with disabilities.
- (6) The extent to which the applicant proposes to provide training in a rehabilitation discipline or area of study in which there is a shortage of qualified researchers, or to a trainee population in which there is a need for more qualified researchers.

(7) The extent to which the proposed project will have beneficial impact on the target population.

(b) *Responsiveness to an absolute or competitive priority.* In determining the application's responsiveness to the application package or the absolute or competitive priority published in the FEDERAL REGISTER., the Director considers one or more of the following factors:

(1) The extent to which the applicant addresses all requirements of the absolute or competitive priority.

(2) The extent to which the applicant's proposed activities are likely to achieve the purposes of the absolute or competitive priority.

(c) *Design of research activities.* In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Director considers one or more of the following factors:

(1) The extent to which the research activities constitute a coherent, sustained approach to research in the field, including a substantial addition to the state-of-the-art.

(2) The extent to which the methodology of each proposed research activity is meritorious, including consideration of the extent to which—

(i) The proposed design includes a comprehensive and informed review of the current literature, demonstrating knowledge of the state-of-the-art;

(ii) Each research hypothesis or research question, as appropriate, is theoretically sound and based on current knowledge;

- (iii) Each sample is drawn from an appropriate, specified population and is of sufficient size to address the proposed hypotheses or research questions, as appropriate, and to support the proposed data analysis methods;
- (iv) The source or sources of the data and the data collection methods are appropriate to address the proposed hypotheses or research questions and to support the proposed data analysis methods;
- (v) The data analysis methods are appropriate;
- (vi) Implementation of the proposed research design is feasible, given the current state of the science and the time and resources available;
- (vii) Input of individuals with disabilities and other key stakeholders is used to shape the proposed research activities; and
- (viii) The applicant identifies and justifies the stage of research being proposed and the research methods associated with the stage.

(3) The extent to which anticipated research results are likely to satisfy the original hypotheses or answer the original research questions, as appropriate, and could be used for planning additional research, including generation of new hypotheses or research questions, where applicable.

(4) The extent to which the stage of research is identified and justified in the description of the research project(s) being proposed.

(d) *Design of development activities.* In determining the extent to which the project design is likely to be effective in accomplishing project objectives, the Secretary considers one or more of the following factors:

(1) The extent to which the proposed project identifies a significant need and a well-defined target population for the new or improved product;

(2) The extent to which the proposed project methodology is meritorious, including consideration of the extent to which—

(i) The proposed project shows awareness of the state-of-the-art for current, related products;

(ii) The proposed project employs appropriate concepts, components, or systems to develop the new or improved product;

(iii) The proposed project employs appropriate samples in tests, trials, and other development activities.

(iv) The proposed project conducts development activities in appropriate environment(s);

(v) Input from individuals with disabilities and other key stakeholders is obtained to establish and guide proposed development activities; and

(vi) The applicant identifies and justifies the stage(s) of development for the proposed project; and activities associated with each stage.

(3) The new device or technique will be developed and tested in an appropriate environment;

(e) *Design of demonstration activities.* In determining the extent to which the design of demonstration activities is likely to be effective in accomplishing the objectives of the project, the Director considers one or more of the following factors:

(1) The extent to which the proposed demonstration activities build on previous research, testing, or practices.

(2) The extent to which the proposed demonstration activities include the use of proper methodological tools and theoretically sound procedures to determine the effectiveness of the strategy or approach.

(3) The extent to which the proposed demonstration activities include innovative and effective strategies or approaches.

(4) The extent to which the proposed demonstration activities are likely to contribute to current knowledge and practice and be a substantial addition to the state-of-the-art.

(5) The extent to which the proposed demonstration activities can be applied and replicated in other settings.

(f) *Design of training activities.* In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Director considers one or more of the following factors:

(1) The extent to which the proposed training materials are likely to be effective, including consideration of their quality, clarity, and variety.

(2) The extent to which the proposed training methods are of sufficient quality, intensity, and duration.

(3) The extent to which the proposed training content—

(i) Covers all of the relevant aspects of the subject matter; and

(ii) If relevant, is based on new knowledge derived from research activities of the proposed project.



- (4) The extent to which the proposed training materials, methods, and content are appropriate to the trainees, including consideration of the skill level of the trainees and the subject matter of the materials.
- (5) The extent to which the proposed training materials and methods are accessible to individuals with disabilities.
- (6) The extent to which the applicant's proposed recruitment program is likely to be effective in recruiting highly qualified trainees, including those who are individuals with disabilities.
- (7) The extent to which the applicant is able to carry out the training activities, either directly or through another entity.
- (8) The extent to which the proposed didactic and classroom training programs emphasize scientific methodology and are likely to develop highly qualified researchers.
- (9) The extent to which the quality and extent of the academic mentorship, guidance, and supervision to be provided to each individual trainee are of a high level and are likely to develop highly qualified researchers.
- (10) The extent to which the type, extent, and quality of the proposed research experience, including the opportunity to participate in advanced-level research, are likely to develop highly qualified researchers.
- (11) The extent to which the opportunities for collegial and collaborative activities, exposure to outstanding scientists in the field, and opportunities to participate in the preparation of scholarly or scientific publications and presentations are extensive and appropriate.

(g) *Design of dissemination activities.* In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Director considers one or more of the following factors:

(1) The extent to which the content of the information to be disseminated—

(i) Covers all of the relevant aspects of the subject matter; and

(ii) If appropriate, is based on new knowledge derived from research activities of the project.

(2) The extent to which the materials to be disseminated are likely to be effective and usable, including consideration of their quality, clarity, variety, and format.

(3) The extent to which the methods for dissemination are of sufficient quality, intensity, and duration.

(4) The extent to which the materials and information to be disseminated and the methods for dissemination are appropriate to the target population, including consideration of the familiarity of the target population with the subject matter, format of the information, and subject matter.

(5) The extent to which the information to be disseminated will be accessible to individuals with disabilities.

(h) *Design of utilization activities.* In determining the extent to which the design of utilization activities is likely to be effective in accomplishing the objectives of the project, the Director considers one or more of the following factors:

(1) The extent to which the potential new users of the information or technology have a practical use for the information and are likely to adopt the practices or use the information or technology, including new devices.

- (2) The extent to which the utilization strategies are likely to be effective.
- (3) The extent to which the information or technology is likely to be of use in other settings.

(i) *Design of technical assistance activities.* In determining the extent to which the design of technical assistance activities is likely to be effective in accomplishing the objectives of the project, the Director considers one or more of the following factors:

- (1) The extent to which the methods for providing technical assistance are of sufficient quality, intensity, and duration.
- (2) The extent to which the information to be provided through technical assistance covers all of the relevant aspects of the subject matter.
- (3) The extent to which the technical assistance is appropriate to the target population, including consideration of the knowledge level of the target population, needs of the target population, and format for providing information.
- (4) The extent to which the technical assistance is accessible to individuals with disabilities.

(j) *Plan of operation.* In determining the quality of the plan of operation, the Director considers one or more of the following factors:

- (1) The adequacy of the plan of operation to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, and timelines for accomplishing project tasks.
- (2) The adequacy of the plan of operation to provide for using resources, equipment, and personnel to achieve each objective.

(k) *Collaboration.* In determining the quality of collaboration, the Director considers one or more of the following factors:

- (1) The extent to which the applicant's proposed collaboration with one or more agencies, organizations, or institutions is likely to be effective in achieving the relevant proposed activities of the project.
- (2) The extent to which agencies, organizations, or institutions demonstrate a commitment to collaborate with the applicant.
- (3) The extent to which agencies, organizations, or institutions that commit to collaborate with the applicant have the capacity to carry out collaborative activities.

(l) *Adequacy and reasonableness of the budget.* In determining the adequacy and the reasonableness of the proposed budget, the Director considers one or more of the following factors:

- (1) The extent to which the costs are reasonable in relation to the proposed project activities.
- (2) The extent to which the budget for the project, including any subcontracts, is adequately justified to support the proposed project activities.
- (3) The extent to which the applicant is of sufficient size, scope, and quality to effectively carry out the activities in an efficient manner.

(m) *Plan of evaluation.* In determining the quality of the plan of evaluation, the Director considers one or more of the following factors:

- (1) The extent to which the plan of evaluation provides for periodic assessment of progress toward—

(i) Implementing the plan of operation; and

(ii) Achieving the project's intended outcomes and expected impacts.

(2) The extent to which the plan of evaluation will be used to improve the performance of the project through the feedback generated by its periodic assessments.

(3) The extent to which the plan of evaluation provides for periodic assessment of a project's progress that is based on identified performance measures that—

(i) Are clearly related to the intended outcomes of the project and expected impacts on the target population; and

(ii) Are objective, and quantifiable or qualitative, as appropriate.

(n) *Project staff*. In determining the quality of the project staff, the Director considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. In addition, the Director considers one or more of the following:

(1) The extent to which the key personnel and other key staff have appropriate training and experience in disciplines required to conduct all proposed activities.

(2) The extent to which the commitment of staff time is adequate to accomplish all the proposed activities of the project.

(3) The extent to which the key personnel are knowledgeable about the methodology and literature of pertinent subject areas.

(4) The extent to which the project staff includes outstanding scientists in the field.

(5) The extent to which key personnel have up-to-date knowledge from research or effective practice in the subject area covered in the priority.

(o) *Adequacy and accessibility of resources.* In determining the adequacy and accessibility of the applicant's resources to implement the proposed project, the Director considers one or more of the following factors:

(1) The extent to which the applicant is committed to provide adequate facilities, equipment, other resources, including administrative support, and laboratories, if appropriate.

(2) The quality of an applicant's past performance in carrying out a grant.

(3) The extent to which the applicant has appropriate access to populations and organizations representing individuals with disabilities to support advanced disability, independent living and clinical rehabilitation research.

(4) The extent to which the facilities, equipment, and other resources are appropriately accessible to individuals with disabilities who may use the facilities, equipment, and other resources of the project.

**§ 1330.25 Additional considerations for field-initiated priorities.**

(a) The Director reserves funds to support field-initiated applications funded under this part when those applications have been awarded points totaling 80 percent or more of the maximum possible points under the procedures described in § 1330.23.

(b) In making a final selection from applications received when NIDILRR uses field-initiated priorities, the Director may consider whether one of the following conditions is met and, if so, use this information to fund an application out of rank order:

- (1) The proposed project represents a unique opportunity to advance rehabilitation and other knowledge to improve the lives of individual with disabilities.
- (2) The proposed project complements or balances research activity already planned or funded by NIDILRR through its annual priorities or addresses the research in a new and promising way.

#### **Subpart D – Disability, Independent Living, and Rehabilitation Research Fellowships**

##### **§ 1330.30 Fellows program.**

- (a) The purpose of this program is to build research capacity by providing support to highly qualified individuals, including those who are individuals with disabilities, to perform research on rehabilitation, independent living, and other experiences and outcomes of individuals with disabilities.
- (b) The eligibility requirements for the Fellows program are as follows:
  - (1) Only individuals are eligible to be recipients of Fellowships.
  - (2) Any individual is eligible for assistance under this program who has training and experience that indicate a potential for engaging in scientific research related to rehabilitation and independent living for individuals with disabilities.
  - (3) This program provides two categories of Fellowships: Merit Fellowships and Distinguished Fellowships.
    - (i) To be eligible for a Distinguished Fellowship, an individual must have seven or more years of research experience in subject areas, methods, or techniques relevant to disability and rehabilitation research and must have a doctorate, other terminal degree, or comparable academic qualifications.

(ii) The Director awards Merit Fellowships to individuals in earlier stages of their careers in research. To be eligible for a Merit Fellowship, an individual must have either advanced professional training or experience in independent study in an area which is directly pertinent to disability and rehabilitation.

(c) Fellowships will be awarded in the form of a grant to eligible individuals.

(d) In making a final selection of applicants to support under this program, the Director considers the extent to which applicants present a unique opportunity to effect a major advance in knowledge, address critical problems in innovative ways, present proposals which are consistent with the Institute's Long-Range Plan, build research capacity within the field, or complement and significantly increases the potential value of already planned research and related activities.

## **Subpart E – Special Projects and Demonstrations for Spinal Cord Injuries**

### **§ 1330.40 Spinal cord injuries program.**

(a) This program provides assistance to establish innovative projects for the delivery, demonstration, and evaluation of comprehensive medical, vocational, independent living, and rehabilitation services to meet the wide range of needs of individuals with spinal cord injuries.

(b) The agencies and organizations eligible to apply under this program are described in 45 CFR 1330.2.